Overview of Structural Options for Affiliations Between Community Access Program Consortia Participants[1]

Prepared for the Health Resources and Services Administration

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I. INTRODUCTION

This Issue Brief presents an overview of the range of affiliation[2] options that may be relevant and helpful to Community Access Program ("CAP") consortia in establishing the operational structures to implement their CAP arrangements. It focuses particularly on structure development, including the key terms of a broad, binding affiliation agreement that will guide the implementation of specific collaborative activities conducted by the CAP consortia participants.[3]

In today's highly regulated health care arena, it is of utmost importance that each CAP participant carefully scrutinize the proposed affiliation structure to assure compliance with applicable Federal law (such as tax, antitrust, anti-kickback, and anti-referral statutes) as well as applicable State laws (e.g. licensure laws).[4] Potential legal exposure under these laws can be minimized through careful structuring of collaborative activities and diligent monitoring of performance thereunder. Accordingly, CAP collaborators should seek the assistance of qualified legal counsel and other professional advisors when developing and/or evaluating particular structural options (and conducting appropriate due diligence reviews) to ensure that the arrangement(s) chosen by the participants comply with all applicable legal requirements.

II. AFFILIATION OPTIONS TO STRUCTURE YOUR CAP ARRANGEMENT

A. In the Beginning ... the Informal (Handshake) Agreement.

The least formal type of affiliation is an unwritten or "handshake" agreement between two or more parties. These types of agreements, which often develop through the course of dealings between the parties, are relatively easy to negotiate and allow the parties a great deal of flexibility, limited accountability, and ease in modification or termination.

In the short-term, CAP consortia participants may conduct initial CAP-related activities under informal arrangements while simultaneously evaluating and developing the appropriate operational structure for their CAP arrangement. However, as a long-term strategy, such approach can be more detrimental than beneficial. As a practical matter, the failure to formalize key terms and assumptions in writing makes the arrangement difficult to enforce and increases the likelihood of misunderstandings and disputes, which can undermine the entire consortium.

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[2] The term "affiliation" as used in this Issue Brief is very broad (i.e., it is not a term of art defined in Federal law). There may be a specific definition of this term under a particular State's law—if this is the case, an affected CAP consortia may need to use the term "collaboration" to describe the arrangement.

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[4] For a brief discussion of such potential legal issues, please see CAP Issue Brief: An Overview of Relevant Federal and State Laws and Regulations for Community Access Program Consortia.

Moreover, in order to demonstrate compliance with various Federal (and often, State) laws, for example the anti-kickback statute, the parties must have a written agreement that meets certain regulatory standards. Accordingly, as a long-term approach, CAP consortia participants should explore more formal methods to structure the arrangements for implementation of collaborative activities.

B. Formal Arrangements: The Contractual and Entity-Based Approaches.

Most likely, the long-term operational strategy used to implement particular CAP arrangements will vary among the CAP consortia. To determine an appropriate strategy and approach, the participants of each CAP consortium should examine their goals and objectives, both collectively and individually; the proposed activities to be undertaken by the CAP arrangement (based on the approved CAP grant application and associated business plan); the current relationships between the participants; and the anticipated dealings among the parties, as well as between the consortium and third parties.

In general, CAP consortia participants may want to consider two broad approaches for the design and implementation of their particular CAP arrangement – a contractual approach and an entity-based approach. Under a contractual arrangement, the participants would conduct CAP-related activities by executing and implementing a broad-based, over-arching agreement in conjunction with a series of implementing contracts covering discrete activities. On the other hand, an entity-based approach would entail the establishment of a new "entity" (corporation, partnership, limited liability company) which, in turn would conduct CAP-related activities (and, presumably, assume CAP-related liabilities).

1. The Contractual Approach: "Umbrella" Affiliation Agreement and Specific Implementing Agreements.

In general, parties hoping to undertake multiple collaborative activities may consider entering into a single, broad binding affiliation agreement ("umbrella agreement") which establishes the basic principles that will govern the operational and financial relationship between the parties and that establishes a joint process to plan, develop and direct the collaborative projects within the scope of the affiliation. Consistent with the broad principles described in the "umbrella agreement," the terms and conditions of particular activities are then set forth in specific implementing agreements (as mutually determined by the parties as the result of the joint development and implementation process).[5]

a. Key Terms to Consider and Address in the Umbrella Agreement.

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[5] The parties can accomplish many of the same goals and objectives by executing a non-binding Memorandum of Agreement ("MOA"), along with specific implementing agreements. Although a MOA might contain the same (or similar) terms as an umbrella agreement, because it would not bind the participants to participate in a development and implementation process, the level of commitment to the process itself (or lack thereof) could result in misunderstandings and disputes which could undermine the collaboration.

(1) Joint Development and Implementation Process.

In order to create a structured, deliberate mechanism for jointly planning, developing and implementing the collaborative activities undertaken by the CAP consortium participants, the parties should commit to participating in a joint process. The umbrella agreement should provide the terms of such process, which typically include the formation of a joint steering committee charged with directing the proposed collaborative activities. To maximize the effectiveness of the committee's efforts by increasing the likelihood that the parties' respective decision-making bodies will approve recommendations developed by the steering committee, the committee should be comprised of an equal number of "key" personnel (i.e., Board member(s), senior management staff) designated by each CAP consortium participant. The parties may also want to include representatives of key "stakeholders" (e.g., leaders of influential community-based organizations) or influential government agencies (i.e., public health departments) on the committee if support from these agencies will be critical to achieving the objectives of the CAP arrangement.[6]

The umbrella agreement should state that the joint steering committee will meet at regularly scheduled intervals (e.g., monthly). The committee's primary duties (which should also be set forth in the umbrella agreement) should include: (1) developing and reviewing specific proposed collaborative activities which have been identified by the participants as either short-term or long-term objectives; (2) making recommendations with respect to how such activities should be implemented; and (3) identifying and discussing new collaborative opportunities which may be favorable to the parties. Further, the committee should monitor the progress of implemented CAP-related activities and address and resolve unforeseen issues between the participants which may arise from such activities.

The umbrella agreement should state that all committee recommendations are non-binding on the CAP participants until approved/ratified by each party's governing board and that upon such board approval, the agreed upon activities and attendant terms and conditions will be delineated in specific implementing agreement(s) executed by the appropriate parties.

(2) Establishing Short-term and/or Long-term Priorities and Associated Time-Frames.

In order to guide and promote the effectiveness and efficiency of the joint development and implementation process at the outset of the relationship, the umbrella

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[6] As part of the joint development and implementation process, the parties may also wish to engage consultants and/or develop task forces to function as issue-specific subcommittees of the joint steering committee. These task forces are typically charged with researching, analyzing, evaluating, reporting and making recommendations to the joint steering committee regarding activities and opportunities within their particular subject area.

agreement should include provisions which establish and prioritize the short-term objectives and/or activities (and, if appropriate, associated time-frames) to be addressed by the joint steering committee as its initial "items of business." The scope of such objectives and/or activities should be fairly limited so that the development and implementation process can be effective immediately, and should be consistent with the business plan included in the approved CAP grant application. The parties may want to consider whether long-term objectives should be stated (and/or prioritized) as well.

(3) Overarching Principles Regarding the Governance/Management of Specific Collaborative Activities.

Often, an affiliating party may be restricted in some manner from undertaking or participating in certain activities (e.g., faith-based organizations may be restricted by religious guidelines) or may be required to maintain ultimate control in terms of the governance and management of certain collaborative activities (e.g., federally-funded health centers may not be able to share control in a truly "equal" manner for certain proposed activities within the health center's "scope of project"). If the CAP consortium participants are subject to restrictions which may substantially affect how collaborative activities will be developed and implemented, the parties should identify these restrictions in the umbrella agreement. For example, a Catholic hospital may want to provide expressly in the agreement that the parties agree that no collaborative activities will violate the church's "ethical directives" for health care. Similarly, a federally qualified health center ("FQHC") may want to establish clearly that the CAP consortium will not undertake any activities which could adversely impact the FQHC's status or eligibility as a federally qualified health center. Establishing these parameters and principles at the outset will promote efficiency with respect to the development and implementation process and could avoid the break down of discussions because of "deal-breakers" that could have been resolved if identified and discussed initially.

(4) Preferred and/or Exclusive Relationship Regarding Certain Activities.

The CAP program is generally not intended to create exclusive "vehicles" for collaboration. Nonetheless, if the CAP consortium participants have invested substantial time and resources and have established a good, working relationship, they might consider creating some form of preferred relationship for future collaborations. If the parties intend to establish a preferred relationship, the umbrella agreement should include the specific parameters and details of such relationship.

The range of preferred relationships is extremely broad and should be carefully tailored to the circumstances of each CAP consortium and its participants. Examples include: maintaining a non-exclusive relationship; defining certain collaborative activities which will not be discussed with other parties; employing best efforts to include the affiliating party(s) in all relevant discussions with other third parties for certain activities or types of activities; and offering the other party(s) a "right of first refusal" with respect to certain collaboration opportunities. Please be mindful that

certain forms of federal and/or state funding received by a CAP consortium participant may restrict the ability of such party to establish a preferred or exclusive relationship in certain cases. A FQHC, for example, must retain the ability to contract with third parties as the health center governing board may deem necessary to assure appropriate access and availability of primary health care services provided to its target population.

(5) The Parties' Financial Expectations and Commitments for the "Costs" of Participation in the CAP Arrangement.

The umbrella agreement should reference the agreed-upon budget included within the approved CAP grant application and identify the CAP grant as the (or one of the) primary sources of reimbursement for the costs incurred for performing CAP-related activities. Further, the umbrella agreement should establish an agreed upon mechanism and/or formula for covering unbudgeted and unanticipated costs including, but not limited to, reasonable expenses incurred by the joint steering committee members (or by an appointed task force) in performing its functions and/or fees and expenses of approved consultants, legal counsel or other external advisors who provide services to further the CAP-related activities.

(6) Confidentiality.

If the CAP consortium participants have executed a separate confidentiality agreement, that agreement should be explicitly referenced and incorporated as part of the umbrella affiliation agreement. If the participants have not executed such agreement, provisions designed to protect the parties from the unauthorized disclosure of confidential and/or proprietary information that may be exchanged in developing and implementing CAP-related activities should be included in the umbrella agreement.

Typically, confidentiality provisions include a broad definition of the confidential information to be protected by the agreement, as well as what kind of information is not considered "confidential."[7] Other common terms include:8

- The allowable uses and disclosures of confidential information;
- Prohibitions and/or limitations against all non-specified uses and disclosures without the written consent of the other party(s);

[7] Typically, confidential information does not include information which is, or becomes, publicly available (not as result of disclosure by an affiliating party), or which becomes publicly available on a non-confidential basis from a source which is not prohibited from disclosing such information.

8 The parties should ensure that all confidentiality provisions are drafted in accordance with applicable federal and State law.

- The return of confidential information promptly, and survival of confidentiality obligations, upon the expiration or termination of the CAP arrangement; and

- Remedies for the unauthorized disclosure of confidential information by a party(s), its officers, employees and/or agents, which should include the right to enjoin the other party(s) from any disclosure of confidential information.

(7) A Dispute Resolution Provision Which Promotes Informal Resolution.

The CAP consortium participants should consider establishing a dispute resolution clause which promotes an informal resolution mechanism over a formal, externally-based mechanism (i.e., arbitration and/or mediation), so as to support an enduring affiliation between the parties. Collaborative arrangements are much more likely to survive if the parties can resolve their disputes and conflicts by avoiding formal and adversarial mechanisms.

In particular, it may be preferable to create an informal resolution process whereby the parties must first attempt to resolve any dispute (subject to good cause, emergency-type exceptions) through the informal discussions of the joint steering committee or the executive management of each CAP participant. If the dispute cannot be resolved in this manner within a reasonable, specified time-frame (e.g., thirty (30) days), the parties can agree that the dispute will be submitted to an externally-based process such as arbitration, mediation, or another similar process.

(8) Termination/Modification.

The umbrella agreement should state the circumstances under which an individual CAP participant can withdraw from the CAP arrangement, with or without cause. Cause may include a party's filing for bankruptcy (or similar action), failure to comply with a material term of the umbrella agreement (or of any implementing agreement(s) which may be created as a result of the joint development and implementation process) or the party's execution of a merger, affiliation or other relationship which adversely impacts upon the consortium's ability to achieve the stated objectives of the CAP arrangement. Because certain CAP-related activities involve an extensive outlay of funds (e.g., the purchase of management information systems ("MIS")), some of which may be provided by the individual CAP consortium participants, the consortium participants may want the umbrella agreement to include financial penalties for a participant's early withdrawal from the CAP arrangement

In addition to terms by which a particular CAP participant can withdraw from the CAP arrangement, the umbrella agreement should include general termination provisions for the arrangement as a whole. Further, as a general policy, specific implementing agreement(s) executed by the parties should continue in effect unless such

agreement(s) is terminated in accordance with its own terms.

(9) Patient Freedom of Choice/Referrals.

If the CAP consortium participants include potential patient referral partners (e.g., a hospital and a health center), the parties may be able to lessen federal anti-kickback exposure by specifying in the umbrella agreement, and operating in accordance with, the fundamental principle that any and all health care professionals employed by, or under contract with, a party, retain sole and complete discretion to refer a patient to any and all providers that, in such professional's independent medical judgment (and subject to any valid restrictions which may be imposed by the patient's managed care plan), best meet the health care requirements of such patient.

(10) Non-Assignment.

Given the unique attributes of each CAP consortium participant and relationships among the parties, we suggest that the umbrella agreement contain a non-assignment clause limiting the ability of one party to assign, delegate or transfer its obligations or rights to another party without the written consent of the other affiliating party(s).

b. Specific Implementing Agreements.

Whether the agreed upon activities (and attendant terms and conditions for such activities) are developed by the CAP consortium participants through a joint development and implementation process established via an umbrella affiliation agreement or through more informal mechanisms, the participants should ultimately execute binding implementing agreements codifying the applicable and agreed-upon terms and conditions for each specific activity.[9] Such agreements may be executed among the CAP consortium participants or between a third party and the consortium itself. Regardless of the parties, the implementing agreements should, among other things, include provisions that allow the parties to revisit the agreements and change the terms as may be appropriate over time. In addition, the effective date of an implementing agreement should be subject to the completion of any due diligence review which may be necessary or appropriate, as well as the assurance and/or receipt of any and all necessary and pertinent statutory and regulatory approvals.

Examples of definitive agreements which CAP consortium participants may use to implement CAP-related activities include:[10]

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[9] Most CAP arrangements encompass a number of arrangements between the parties which may require separate agreements drafted in a manner which meets different safe harbors under the anti-kickback statute, e.g., a combination of a lease or purchase agreement for equipment and a contract for the purchase of clinical and/or administrative services.

[10] For a more extensive discussion of implementing agreements, please see the upcoming CAP Issue Brief regarding vendor agreements (to be issued at a later date).

- Contracts to create a virtual health care system among the participants by purchasing specific health care, management or administrative services, providing for the co-location of services and/or developing and operating new site locations.

- Contracts between the consortium and an individual participant for the purchase of clinical, management or administrative support services.

- Contracts between the consortium participants to share services (i.e., administrative and financial services) and jointly purchase goods and services.

- Leases for space, equipment and/or personnel.

c. Issues Pertaining to the Contractual Approach.

Many successful affiliations have been established and operated under a contractual approach. However, should the CAP consortium choose such an approach, it should be mindful of specific issues with respect to contractual arrangements.

(1) Antitrust law.

As discussed in the previously issued CAP Issue Brief providing an overview of potential legal issues, federal antitrust laws prohibit activities among competitors and potential competitors which are considered inherently "anti-competitive" or which are deemed to be anti-competitive when balanced against their potential pro-competitive effects. One way to shield your arrangement from potential antitrust exposure would be to structure the arrangement to comply with an applicable "safety zone."

One of these safety zones covers integrated provider networks. A collaboration that meets the criteria for an integrated provider network can negotiate and contract with third parties as a single entity, on behalf of its participants. In order to fall within the safety zone, the CAP consortium participants must share substantial financial risk (i.e., capitation payments and fee withholds) and demonstrate other indicia of financial integration (e.g., participants each make substantial capital investments in the CAP arrangement, each participant executes a participating provider contract that provides for capitation payments with risk pools, and/or participants engage in coordinated activities/services that the individual participants could not do by themselves). In addition, the consortium must not include more than 30% of primary care or specialty physicians in the relevant market if it is a non-exclusive arrangement, or if exclusive, not more than 20% of primary care or specialty physicians in the relevant market.

These parameters apply equally to contractual arrangements as to other forms of collaborations. However, should the CAP consortium participants determine

that an entity-based approach (described below) would be a more appropriate structure, the entity, by virtue of its organizational structure, may more easily satisfy the criteria for integration. On the other hand, should the participants decide to use a contractual approach, unless they can demonstrate that the arrangement satisfies all criteria for sufficient integration, it may be prudent for the participants to conduct only those activities permitted under safety zones promulgated for non-integrated providers. Typically, such activities must be conducted through a third party and can only involve the collection and sharing of non-current information that has been aggregated and that does not pertain to competitively sensitive (e.g., price-related and other financial) data. With respect to contract negotiations, the consortium would be able to act as the participants' agent under the "messenger model." However, the participants could not engage in collective negotiations, rather the consortium would have to negotiate for each participant individually. Further, each participant would have to make unilateral, independent decisions regarding whether to accept or reject specific contracts.

(2) Health Insurance Portability and Accountability Act (HIPAA).

As discussed in the previously issued CAP Issue Brief regarding HIPAA and the standards to protect the privacy of individually identifiable information, the privacy regulations require that covered entities obtain patient consent and authorization, as applicable, prior to disclosing individually identifiable health information. CAP consortium participants that are purchasing MIS to share health information must ensure that the system is "HIPAA-compliant"and that their agreements both among the CAP consortium participants and with outside vendors include clauses that mandate compliance once the regulations go into effect.

The regulations create an exception to certain HIPAA requirements for arrangements classified as "organized health care arrangements." To be classified as such under the regulations, the entity must perform services under: (1) a clinically integrated care setting in which individuals typically receive care from more than one provider; or (2) an organized system of health care in which more than one covered entity participates and in which the entities hold themselves out to the public as a joint arrangement and participate in at least one of the following activities: utilization review, quality assessment and improvement activities, or payment activities in which the entities share financial risk. Entities that are part of an organized health care arrangement are permitted to use a joint consent form and a joint notice of privacy practices. Further, they do not need to comply with the requirements for business associate contracts for other entities in the arrangement. Most important for CAP consortia participants, all participating entities are permitted to share information for treatment, payment and health care operations with other entities in the arrangement.

If the CAP consortium participants determine that an entity-based approach (described below) would be a more appropriate structure than a contractual affiliation, they may be able to take advantage of the flexibility afforded organized health care arrangements. Similar to antitrust, the entity, by virtue of its organizational structure, may be more likely to satisfy the relevant criteria. The benefits of such an

arrangement would be the ease of sharing information among participants for treatment, payment and health care operations.

(3) Corporate liability issues.

If the CAP consortium participants engage in the joint delivery or marketing of health care and/or health care-related services, a contractual approach may not shield individual participants from liability (even for the actions of other participants!) unless certain protections are included in the contracts between the consortium participants. The participants may be able to manage such liabilities and risk associated through appropriate indemnification and insurance provisions.[11] However, the general principle of corporate liability, wherein individual participants (owners, members) in a corporate entity are shielded from liabilities arising from corporate actions, will not attach to a contractual affiliation.

(4) Other.

If the CAP consortium intends to act as a risk-bearing entity or assume insurance functions under state law, the participants must conduct a careful and thorough review of state insurance laws to ensure that a collaboration structured under a series of contracts can legally assume risk.

One of the fundamental activities of many CAP consortia is the development of a joint purchasing program, in particular the joint purchasing of MIS. However, when negotiating for goods or services furnished by vendors, the vendors typically require a single legally binding signatory for the applicable contract. In our experience, MIS vendors have been particularly concerned regarding this issue. If the CAP consortium chooses to operate under a contractual affiliation, most likely one CAP participant (generally the CAP grantee) would execute vendor contracts on behalf of the consortium. In turn, the purchaser entity would have to execute contracts with the other participants to ensure the commitment of all participants (i.e., so the purchaser does not get left "holding the bag").

2. Establishment of a New Entity.

Health care providers often affiliate by creating a new and separate corporate entity that is jointly owned and/or controlled by the affiliating parties (as opposed to the affiliating parties being owned/controlled by the new entity). Similar to the joint steering committee discussed under the umbrella affiliation agreement option, the governing body of the new entity typically is comprised of representatives of the organizations that create the new entity and often also

[11] It may be reasonable for contractual approaches to include mutual indemnification obligations to protect each participant organization by requiring the reimbursement of costs incurred by a participant directly arising from liabilities created/caused by the actions (or omissions) of another collaborating participant.

includes “at large” members who may represent influential non-affiliating organizations or constituencies within the relevant community.

CAP consortia that pursue an entity-based approach to affiliation may be structured as either for-profit or nonprofit corporations, general or limited partnerships, or as limited liability companies (“LLC”). The option chosen should reflect the goals and purposes of the new entity and the CAP consortium participants’ expectations regarding governance, liability and risk, return on investment and taxation.

A key, and typically beneficial, characteristic of forming a new corporate entity is that the founding organizations maintain their independent corporate identities and governance structures. The establishment of a new, jointly-created entity with one set of collaborators does not typically preclude collaborations with other parties for other purposes. In this regard, the parties may create and enjoy the benefits of a preferential relationship with one another for a particular collaboration, while preserving each party's ability to maintain positive relationships and enter into affiliations with other parties.

Under the corporate form of affiliation, as a general rule, the sharing of control and risk extends only to the new entity’s activities, thereby shielding the owners/founders from the liabilities generated by the entity. Also, in a for-profit corporate structure or LLC, each party's share of any profits or downside financial risk associated with the new entity is equivalent to its percentage ownership in the entity.[12] Once a new entity is established and capitalized, its ability to make decisions through its own governance structure usually accelerates the speed with which joint activities can be initiated and problems solved.

The capitalization of a for-profit entity or a LLC is usually accomplished through the parties’ contributions of cash or other financial resources in exchange for a percentage of ownership. If a provider has little or no financial capital to contribute, it may "purchase" its share of ownership by contributing valuable in-kind services or expertise (subject to applicable State law requirements).[13] In addition, Board seats are commonly allocated according to the relative equity positions of the parties establishing the entity, although Board seats can be allocated in a different manner (i.e., equally divide the seats notwithstanding disproportionate equity ownership).

If the new entity is formed as a nonprofit corporation, financing may be achieved through grants, contributions and/or loans. Surpluses generated by the nonprofit entity may not be distributed to the affiliation partners for private benefit purpose (i.e. the restriction against “private inurement”). The parties must agree as to the allocation of Board seats and, if the new entity is formed as a membership corporation, the number and identity of members.

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[12] A careful analysis under the Federal anti-kickback statute is advisable in this regard.

[13] Please note that some States have “gift of public fund” restrictions that may limit the ability of a public entity to invest in a for-profit joint venture.

Limited liability companies combine the tax benefits of partnerships (no taxes paid by the LLC itself, only the individual owners) with protection against personal liability similar to corporations. Accordingly, the net income of the LLC is taxed only when distributed to members/owners. Governance of the LLC is typically defined in an operating agreement and defined by state law.

If the CAP consortium chooses to pursue an entity-based approach to affiliation, the consortium would have to draft and execute corporate documents (e.g., articles of incorporation, bylaws, a shareholder agreement, a limited liability company operating agreement, a partnership agreement) to establish and structure the newly formed entity. Further, the new entity would have to execute specific implementing agreements (e.g., vendor agreements, employment agreements, leases) to implement the CAP-related collaborative activities.

III. CONCLUSION.

This Issue Brief has presented an overview a range of affiliation options that may relevant and helpful to Community Access Program ("CAP") consortia participants in implementing their CAP arrangements. Each CAP consortium will likely chose (or has chosen) to structure its affiliation/collaboration through diverse means; therefore, some of the options identified herein may not be relevant to a particular consortium. However, the goal of this Issue Brief is to identify and explain different structural options available to CAP consortia that are still in the process of determining the ideal and/or mutually beneficial method for structuring collaborative arrangements which will facilitate implementation of their objectives. For those consortia who have already made such a determination but may not have considered some of the options identified, or a particular aspect of an option, this Issue Brief may be of assistance in deciding whether the current affiliation structure/methodology should be re-examined.